DEPARTMENT OF HEALTH & HUMAN SERVICES

April 14, 2003

Food and Drug Administration
Rockville MD 20857

RECEIVED
OCT 9 2003
RatnerPrestia

FAP 2234
Natamycin

Arkion Life Sciences
c/o Mr. Franklin Carter
1082 Duna Drive
Laramie, Wyoming 82072

Dear Mr. Carter:

We have completed our review of your most recent letter concerning your food additive petition of July 31, 2001, for natamycin. The petition seeks to amend Federal food additive regulations to permit the use of natamycin in complete broiler chicken feeds for the purpose of retarding the growth of *Aspergillus parasiticus* in the feed for up to 14 days. Your letter, which was undated but received on March 20, 2003, was your response to our letter of March 13, 2003, on the topic. Your letter included a copy of your revised label.

The results of our review of your letter are as follows:

Except for what you considered to be typographical errors in two paragraphs of our letter of March 13, 2003, you said you accept all the suggestions we made in that letter for modifications to your proposed label for natamycin, and to your proposal for amending the Federal food additive regulations to permit the use of natamycin in feeds.

The sections of our letter you deem as containing typographical errors are those dealing with specifications of the composition of the natamycin premix used in your experiments. We stated in our letter that natamycin should be specified as containing the following substances in grams per pound: calcium carbonate, 432.708 (433 g); natamycin, 11.292 (11 g); and lactose, 10 g. This specification does not contain typographical errors as claimed. It is actually based on statements contained in your petition (appendix C1: Premix Batch record & Analysis), and certified by your investigator (Dr. Roger Wyatt of the University of Georgia, Athens), that this was the composition of the natamycin premix used in your experiments. A copy of the pertinent section of your petition is attached. There is a discrepancy between this specification, which you previously certified as being correct, and the one you are now asking us to adopt (in grams/lb): calcium carbonate, 434; natamycin, 10; and lactose, 10. Please clarify the discrepancy.

We have the following comments about your revised label:

The label contains two sections entitled "caution." We suggest that you eliminate the first "caution" section by combining the statements under it with those under your "directions for use" to form a new section on "directions for use". The new "directions for use" should read as follows: "1 pound (1 lb) or 0.45 kilograms (0.45 kg) of NSURE per ton (908 kg) of

complete broiler feed. Thoroughly mix NSURE into the dry components of the feed before adding the liquid components. Use NSURE treated feeds within four weeks of treatment."

Please include the contact telephone number for Arkion Life Sciences after the company name, logo, and address.

Please review our comments on your revised proposed label to determine if you find them to be acceptable, and clarify the discrepancy between your specifications for the composition of natamycin premix. We will review your response to this letter, and use any suggestions you make that are appropriate to initiate the process for publishing the notice of approval in the Federal Register.

Thank you for informing us about the transfer of the assets of DUCOA, including FAP 2234, to Arkion Life Sciences, 3521 Silverside Road, Wilmington, Delaware 19810. We will update our records accordingly.

Please do not hesitate to write us, or telephone Dr. Henry Ekperigin at 301-827-0174, if you have questions regarding this letter. Refer to FAP 2234 when making such inquiries.

Sincerely,

Sharon O. Benz for

George Graber, Ph.D.
Director
Division of Animal Feeds
Center for Veterinary Medicine

Enclosure